REMARKS

This amendment and Remarks are filed in response to the Office Action dated November 8, 2006 wherein all pending claims stand rejected.

Amendment of Claims and Support in the Specification

Claims 1-30 are canceled. New claims 31-42 are added.

Claim 31, step a is supported on page 28, lines 1-6 and on page 29, lines 9-18; step b) is supported on page 24, section c), lines 36-37 and on page 25, lines 1-9; step c) is supported on page 36, lines 34-37 and page 37, lines 1-10; steps d) and f) are supported on pages 52-53, lines 22-32 and 1-14, respectively, and step e) is supported on page 61, lines 1-24.

Claim 32 is supported on page 12, lines 31-33.

Claim 33 is supported on page 13, lines 5-26 and page 60, lines 6-26.

Claim 34 is supported on page 13, lines 5-26, page 56, lines 2-5 and page 60, lines 6-26.

Claim 35 is supported on page 28, lines 25-37.

Claim 36 is supported on page 28, lines 25-37.

Claim 37 is supported on page 37, lines 1-10.

Claim 38 is supported on page 37, lines 1-10.

Claim 39 is supported on page 36, lines 13-20.

Claim 40 is supported on page 37, lines 22-35 and Tables 3 and 4, pages 47 and 48.

Claim 41 is supported on page 70, lines 23-29.

Claim 42 is supported on 32, lines 6-14.

The newly submitted claims are fully supported in the specification. No new matter is included.

Rejections under 35 USC § 112

Claims 2-5, 7-9 and 21-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at

the time the application was filed, had possession of the claimed invention.

Examiner argues that the specification fails to disclose a method as required by claim 21 of preparing a neo-cartilage construct comprising isolated chondrocytes seeded into a support matrix containing a plurality of pores, and then subjecting the construct to conditions of static, constant or cyclic hydrostatic pressure, atmospheric pressure or non-pressure conditions. Chondrocytes seeded into a matrix will not be a neo-cartilage construct since cartilage has not been produced. The neo-cartilage construct results only after the chondrocytes seeded in the support have been treated as disclosed in the specification at 5 page 38, lines 19-32 and page 39, lines 7-11, by using hydrostatic pressure at a certain pressure and freguency and time above atmospheric, perfusion at a certain flow rate for a certain time and a resting period at atmospheric pressure for certain times. Claim 21 does not require using any pressure above atmospheric and any resting period at atmospheric pressure due to the claim encompassing atmospheric pressure or non-pressure conditions, conditions for applying pressure of zero MPa and zero time, and zero time for applying a resting period. The claim does not require perfusion that the specification indicates is required to produce the neo-cartilage construct.

Applicants disagree. However, in order to advance the prosecution, Applicants canceled claim 21 and added new claim 31 comprising steps a-f. These steps are fully supported in the specification in various places and on various pages. Specific pages dealing with each step are listed above.

The specification fails to disclose a gel as being alternative to specific gels as in claims 22 (line 2), 26 (line 3) and 27 (line 3). As disclosed in the specification, the specific gels are the gel to be used, and are not alternative to a gel.

Applicants disagree. The term gel or gels, as such has been eliminated from the claims.

The specification fails to disclose a honeycomb and honeycomb lattice being alternatives as in claim 22 (line 4). When a honeycomb lattice is present, this is the honeycomb, and not the alternative of a honeycomb.

Applicants disagree. Both honeycomb and honeycomb-like lattice are disclosed in the specification on page 30, lines 4-14. Applicants reworded the claims to describe the honeycomb and the honeycomb-like lattice, as described in the specification.

The specification fails to disclose periods required in claims 28 and 30 of "4 hours per day" and "20 hours per day". Additionally, a time of "about 7 days" for a resting period as required in claims 28 and 30 is not found in the specification.

Applicants disagree. Applicants reworded claims to correspond to exact description in the specification, as indicated above. The support for the new claim is found on page 37, lines 1-10.

Applicants respectfully submit that with the newly submitted claims, the rejections under 35 USC 112, first paragraph are overcome and should be withdrawn. It is so requested.

Rejections under 35 USC § 112, Second Paragraph

Claims 2-5, 7-9 and 21-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Examiner submits that reciting in claim 21 "zero MPa to about 10 MPa", "zero to about 24 hours" and "zero to about 24 hours per day" makes unclear as to conditions required since when zero the condition recited is not present. Due to the recital of "zero", claim 21 does not require any pressure, any frequency and any resting period. This also applies to reciting "zero" in claim 9, and this claim does not require any pressure and resting period for treating the neo-cartilage construct.

When the resting period precedes the hydrostatic pressure as an alternative to following the hydrostatic pressure in claims 9 and 21, it is not seen how the period can be a resting period since

no hydrostatic pressure has been applied which can be removed to provide a resting.

Applicants disagree. However, to advance the examination, Applicants canceled claim 21 and submit herewith a new claim 31, that claims parameters described in the specification.

In line 7 of claim 21, the difference in static and constant hydrostatic pressure is uncertain. A static pressure would appear to be a constant pressure, or the converse.

Applicants disagree. Applicants canceled the static pressure language from the claims altogether.

Bridging lines 8 and 9 of claim 21, conditions are uncertain that are "non-pressure" and alternative to hydrostatic and atmospheric pressure. The specification fails to describe non-pressure conditions.

Applicants disagree. Non-pressure or rather atmospheric pressure conditions are used for a resting period. To make the intent of the claims clear, applicants redrafted claims as the new claim 31.

In line 4 of claim 21 and where recited in other claims, "neo-cartilage construct" is uncertain as to meaning and scope. It is uncertain how "neo" defines the construct, and how one would know when a construct is neo and not neo.

Applicants disagree, however, in the interest of advancing the prosecution, Applicants canceled the neo-cartilage term from the claims.

Step b) of claim 21 is confusing by requiring implanting the construct into injured or damaged articular cartilage, whereas the claim preamble requires damaged, injured, diseased or aged articular cartilage. Step b) should be consistent with the claim preamble.

Applicants disagree. The prior step b) is now the step e) and this step relates back to the preamble.

In claim 5, the meaning and scope of "superficial cartilage layer" is uncertain. How "superficial" defines the cartilage layer

is unclear. Additionally, where does this layer exist relative to the top sealant and construct in the lesion. Furthermore, claim 5 is confusing as to steps performed by not setting forth clear, distinct and positive method steps.

Applicants disagree. Claim 5 is canceled and the new corresponding claim 41 clarifies this point.

Claim 7 is unclear in lines 4-7 as to the components of the Markush group that are contained and not contained by the cell-contracted collagen. Is glycoprotein the last component, or are other components contained by the contracted collagen. It is suggested "cell-contracted collagen containing proteoglycan, glycosaminoglycan or glycoprotein" be changed to "cell-contracted collagen containing a material selected from the group consisting of proteoglycan, glycosaminoglycan and glycoprotein".

Applicants appreciate Examiner's suggestion and adopted it.

To be clear, claim 9, line 4, should change "hydrostatic cyclic pressure" to --cyclic hydrostatic pressure-- to be consistent with claim 21. Additionally, "constant pressure" line 6 of claim 9 should be changed to --constant hydrostatic pressure-- since the constant pressure in claim 21 is hydrostatic pressure. Claim 9 is dependent on 10 claim 21 via claim 8, and the constant pressure in claim 9 must be hydrostatic pressure since claim 9 cannot broaden claim 21 as to constant pressure required.

Applicants disagree. The rejection is overcome with the new claims where the above points are either corrected or eliminated from the new claims.

In line 12 of claim 9, the perfusion flow rate is unclear by reciting "μL" instead of "μL/min" as in claim 8.

Applicants corrected this omission in claims 39 and 40.

In line 8, claim 9 is unclear as to whether the pressure applied for 7-28 days is the hydrostatic cyclic pressure or the constant pressure previously required. If intended to be the constant pressure, this pressure can be zero, and when zero it is uncertain how pressure can be applied for 7-28 days.

Applicants disagree. Claim 9 is canceled. The new claims do not claim zero pressure.

In line 2 of claim 29, "TRGH" should be in parenthesis and preceded by the full name to be clear as to the meaning of the abbreviation.

Applicants spelled-out the thermoreversible gelation hydrogel in all new claims.

It is believed that with the new claims, all rejections under 35 USC 112, second paragraph have been addressed and corrected.

Rejections under 35 UCS § 102

Claims 21 and 23 are rejected under 35 U.S.C. 102(a) as being anticipated by Smith et al (6,528,052 B1).

The claims are drawn to a method for repairing and restoration of damaged, injured, diseased or aged articular cartilage to form a functional hyaline cartilage. The method comprises preparing a neo-cartilage construct comprising isolated chondrocytes seeded into a three-dimensional support matrix containing a plurality of pores, and subjecting the construct to a static, constant or cyclic hydrostatic pressure, atmospheric pressure or non-pressure conditions, and implanting the construct into the injured or damaged articular cartilage or into a lesion in the articular cartilage.

Smith et al disclose a method for *in vivo*, *ex vivo* or *in vitro* repair and regeneration of cartilage. The cartilage can be articular cartilage (col 1, line 42). In vitro treatment is performed by obtaining cartilage cells from cartilage, applying an interval loading regiment while culturing the cartilage cells in suspension within a scaffold/support, and implanting the resultant tissue or cells into a patient (col 9, lines 23-30, and col. 11, lines 5-9) . The interval loading regiment involves treatment of cartilage or cartilage cells by using conditions of intermittent application of periods of hydrostatic pressure followed by periods of recovery (col 4, lines 25-31, and col 7, line 30 to col 8, line 8). The recovery period can be at 5 atmospheric or low constant

pressure (col 7, lines 48-50).

Smith et al disclose a method for repairing and regenerating cartilage that is the same as presently claimed. The cartilage regenerated will inherently be functional hyaline cartilage.

The presently claimed invention is not disclosed in parent application 10/104,677, and the parent application cannot be relied on for a priority date earlier than the filing date the present application.

Applicants disagree. However, due to the submission of the newly redrafted claims, clearly, the anticipation of the current claims by Smith et al reference cannot be maintained. The new claims contain steps of depositing the bottom and top sealants into the cartilage lesion. No sealant or its use is disclosed in or by Smith et al.

The rejection should be withdrawn. Applicants respectfully request Examiner to do so.

Inventorship

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e) t (f) or (g) prior art under 35 U.S.C. 103 (a).

Inventorship of all claims remains the same.

Rejections under 35 USC § 103

Claims 7 and 22 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Smith et al in view of Vacanti et al (6,027,744) The claims are drawn to the support matrix being prepared from materials including a polymeric thermo-reversible gelling hydrogel (THGH).

Smith et al is described above.

Vacanti et al disclose generating new tissue in a patient by providing a hydrogel containing tissue precursor cells in a support structure, and implanting the hydrogel-containing support structure in a patient (col 1, lines 34-50). The cells can be chondrocytes (col 2, line 64), and the tissue produced can be cartilage (col 4, line 50). The hydrogel can be a reverse-thermosensitive copolymer gel that is liquid below a certain temperature, and which solidifies above a certain temperature (col 14, lines 35-45). The support structure can be formed of polyglycolic fibers (col 12, line 63). Using a hydrogel in a support structure improves the quality of new tissue growth, and the range of tissue shapes and structures that can be grown. In addition, the hydrogel allows diffusion of nutrients and waste products to and away from the cells, which promotes tissue growth (col 1, lines 51-62).

It would have been obvious to use as the scaffold/support of Smith et al, a hydrogel in support structure as disclosed by Vacanti et al to obtain its advantages of improved the quality of new tissue growth, range of tissue shapes and structures that can be grown, and allowing diffusion of nutrients and waste products to promote tissue growth.

Applicants disagree. However, both claims have been canceled and the new claims are dependent on the new claim 31, that contains features not disclosed in either references or in the combination thereof.

In view of the cancellation of the claims the rejection is moot.

Rejections under 35 USC § 103

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al in view of Nevo et al (6,632,651 B1).

Claim 8 requires the matrix seeded with chondrocytes to be perfused with a medium at a flow rate from about 1 μL/min to about 500 μL/min.

Smith et al is described above.

Nevo et al disclose perfusing cells with a medium to maintain viability and growth prior to implanting (col 2, lines 8-15 and col 8, lines 41-43).

It would have been obvious to perfuse cells in the scaffold/support of Smith et al with culture medium to maintain viability and growth of the cells as suggested by Nevo et al. Selecting a preferred flow rate of about 1 μL/min to about 500 μL/min would have been obvious to maintain preferred optimum viability and growth of cells.

Applicants disagree. The claim 8 is canceled and the new claims 39 and 40 claiming this feature are dependent on the new claim 31 that distinguishes the new claims from the cited references. The rejection is moot and should be withdrawn.

Rejections under 35 USC § 103

Claim 9 is rejected under 35 U.S.C. 103 (a) as being unpatentable over the references as applied to claim 8 above, and further in view of Hungerford et al (6,378,527 B1).

The claim requires specific conditions of pressure and frequency for using hydrostatic cyclic pressure, and carrying out perfusion at a flow rate in a range of about 5 μL to about 50 μL and in the presence of about 2% to about 5% oxygen.

Hungerford et al disclose that using a low oxygen level of about 5% when culturing chondrocytes seeded on a scaffold results in enhanced expression of collagen type II and aggrecan, as well as helping maintain chondrocyte phenotype (col 24, lines 14-23).

It would have been obvious to use a low oxygen level of about 5% when culturing chondrocytes in the scaffold/support of Smith et al to obtain enhanced expression of collagen type II and aggrecan, as well as helping maintain chondrocyte phenotype as suggested by Hungerford et al. The pressure and frequency for hydrostatic cyclic pressure of the claim would have been obvious from the pressure and frequency disclosed by Smith et al. The perfusion flow rate would have been obvious for reasons set forth above. Since the constant pressure and resting period claimed can be zero, the claim does not

require a constant pressure and resting period.

Applicants disagree. The claim 9 is canceled and thus the rejection is moot. New claim 40 is dependent on claims 31-38 with many distinguishing features incorporated therein. Thus the use of decreased percentage of oxygen does not stand alone and *per se* does not make claims obvious.

The rejection is moot and should be withdrawn.

Rejections under 35 USC § 103

Claim 2 is rejected under 35 U.S.C. 103 (a) as being unpatentable over Smith et al in view of Wise et al (American Surgeon) and Rhee et al (5,475,052), and if necessary in further View of Rhee et al (5,565,519).

The claim requires applying a layer of top sealant over the cartilage implanted into a lesion.

Smith et al is described above.

Wise et al disclose using a collagen-polyethylene glycol sealant to seal leaks after liver transplantation.

Rhee et al ('052) disclose using a collagen-polyethylene glycol matrix (cols 15-17, and col 20, line 60 to col 23, line 67) for implant applications.

Rhee et al ('519) disclose using a collagen-polyethylene glycol conjugate for ophthalmic applications (cols 9-20).

It would have been obvious to seal a defect after implanting cartilage tissue in a defect as disclosed by Smith et al using a collagen-polyethylene glycol sealant as suggested by Wise et al using this sealant and Rhee et al using a collagen-polyethylene glycol matrix for implant applications. It would have been obvious that sealing the defect after implanting will be advantageous to prevent contamination and infection at the site of the defect. If needed, Rhee et al ('519) would have further suggested using a collagen-polyethylene glycol sealant from disclosing using a collagen-polyethylene glycol conjugate for ophthalmic applications. Formation of a superficial cartilage layer will be inherent when the defect containing the sealed implanted construct heals.

Applicants disagree. Claim 2 is canceled. However, the combination of the above references, as Examiner is suggesting is not obvious. First, Smith reference does not utilize sealant disclosed in the current invention and does not suggest use of any sealant.

Smith, et al ('052) teaches methods for *in vivo*, *ex vivo* and *in vitro* repair and regeneration of cartilage and collagen and also for bone remodeling. Smith reference concerns a discovery that intermittently and repeatedly applied hydrostatic pressure during interval loading periods influences articular chondrocyte gene expression, elicits load-dependent collagen type II expression, decreases a matrix metalloproteinase expression, results in regeneration of diseased or damaged cartilage and collagen and permits the *de novo* formation of mesenchymal or mesenchymally-derived cells within a matrix.

Applicants point out to the Examiner their claim utilizes two sealants and that the Smith reference deals with treatment of the diseased or injured cartilage or with production of the new cartilage by providing conditions, the algorithm, for the cells or tissue to recover, repair itself or form the new tissue. At best the Smith reference may be related to the current invention as the reference showing that certain conditions permit the cartilage tissue to recover.

Examiner argues that the use of the sealant would be obvious to close the wound and protect it from the outside environment. However, the use of the current adhesive sealant, and it should be noted, the use of the specific polyethylene glycol cross-linked with alkylated, preferably methylated collagen sealant, has been found, surprisingly, to result in the newly formed structural tissue layer, herein called superficial cartilage layer, that is, with time, integrated into the synovial membrane covering the uninjured cartilage.

Applicants specification, Figures 10B and 12A and 12B clearly show the formation of the superficial cartilage layer compared to the untreated lesion (Figure 10A) and formation of fibrocartilage

in defects that were not covered with the adhesive sealant, seen in Figures 11A and 11B.

Should the Examiner's argument be valid, then the untreated defect, as seen in Figures 11A and 11B, could be contaminated and/or infected during and after surgery. Quite clearly, the arthroscopic surgeries are performed in sterile conditions and typically do not result in contaminations or infections and expectation that the site would be contaminated during surgery is not a reason to use the sealant. During arthroscopic procedures using implant, such implant is typically attached and secured with microsutures.

The current results show that when, instead of the microsutures, the adhesive sealant is used and applied over the implant, this particular sealant not only seals the implant within the lesion cavity but it does integrates with the surrounding tissue and within certain period of time, typically from one week to several months, (Spec., page 18, lines 16-19) leads to formation of what is called here the superficial cartilage layer, that is integrated into the native synovial membrane of the surrounding tissue.

Moreover, while it seems obvious to Examiner to do so, it is not currently the practice to cover the implant with any kind of glue when the various implants are used for repair of the cartilage. Additionally, as already pointed out, the invention does not utilize any kind of sealant but a specific tissue adhesive that must contain derivatized collagen cross-linked with polyethylene glycol and only this type of the tissue adhesive was shown to result in formation of the superficial cartilage layer.

Smith does not in any way suggest, imply or disclose use of any sealant or tissue adhesive, top or bottom, and it definitely does not give any notion that such use could lead to formation of the protective superficial cartilage layer overgrowing the treated cartilage. Thus to make this invention obvious, Smith alone or in combination with other cited references would have to suggests,

disclose or indicate that such superficial layer is formed, and such suggestion is nowhere to be found and, in fact, without using this specific sealant, **such superficial cartilage layer is not formed.**

Applicants respectfully submit that none of the references or their combination provides any kind of suggestion or implies that such formation would happen.

Wise et al discloses sealant used for bile leaks in liver transplantation. The specific material, absorbable polyethylene glycol/collagen biopolymer sealant (CT3 Surgical Sealant, Wise, page 1, lines 2 and 3), disclosed by Wise is a true surgical sealant that acts as a sealant in an acute situation, and is used to stem the flow of bile after/during a liver transplantation. Examiner should note that the sealant Wise is using is not derivatized polyethylene glycol or polyethylene glycol cross-linked with derivatized (alkylated, particularly methylated) collagen.

Additionally, Examiner should note, that the liver is the soft tissue compared to the hard cartilage tissue subjected constantly to pressure, rotation, shearing and other forces employed during knee or joint movements and rotation. There is no need for long term presence of the sealant following the transplantation and the sealant is therefore quickly absorbable (Wise, line 2, page 1).

Applicants respectfully submit that the Wise' use of the **different sealant** for **different tissue** and **different medical application** does not make the current invention obvious. How could application of the different sealant to the bile leakage during liver transplantation suggest that the different sealant would be useful to hold the joint implant in place in a hard joint surface environment long enough, and also that it would interact with and integrate into the patient own tissue overgrowing the cartilage lesion.

It is also worth noting that the cartilage lesion is a place where currently used implantations require 50-100 microsutures to keep the implant in place. There is no assurance from the Wise

reference that the kind of joint stresses, such as knee bending or continuous passive motion that the Wise sealant would be subjected to would be possible, since there are no such stresses in the bile reconstruction system.

Rhee et al ('052) teaches various collagen-synthetic polymer materials for use as the matrices. However, Examiner will note that these materials are suitable to be used for preparation of various collagen-synthetic polymer matrices and biocompatible implants but not for use as tissue sealants. Additionally, not even the use for preparation of implants for joint cartilage is disclosed in this reference. Since no use as the sealant is disclosed and since the use and materials are different and the purpose of their use is different, Applicants respectfully argue that the reference alone or in combination with other references does not even point out to the current invention not to say making it obvious.

Rhee et al ('519) teaches conjugates for ophthalmic application.

Not to repeat the arguments already submitted above, Applicants respectfully submit that the ophthalmic use does not in any way suggest the use of the sealant in hard tissue, such as the joint cartilage. Applicants direct Examiner's attention to the col. 19, lines 26 to lines 67 where the various uses of the various forms of chemically modified collagen covalently cross-linked with synthetic hydrophilic polymers, such as polyethylene glycol cross-linked with methylated collagen, are described as useful for ophthalmic use, devices and materials that are relatively transparent to visible light. Disclosed uses are, for example, vitreous humor replacement, corneal shields, artificial corneal implants and/or delivery of various drugs.

There is no teaching or suggestion in any of the cited references to combine them in a general or specific way to obtain Applicants present invention.

Applicants submit that the present invention is not obvious in

view of these references, alone or in any kind of combination.

Reconsideration and withdrawal are respectfully requested.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CPR 3.73(b).

Claims 2, 7-9 and 21-23 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 6,949,252 B2 or claims 1-20 of U.S. Patent No. 6,528,052 Bl in view of Wise et al and Rhee et al ('052), and if necessary in further view of Rhee et

al ('519).

For the type of reasons set forth in the 103 rejection, it would have been obvious to seal a defect after implanting the cartilage construct of the claims of the patents using a sealant as suggested by Wise et al and Rhee et al ('052), and if needed Rhee et al ('519). Formation of a superficial cartilage layer will be inherent when the defect containing the sealed implanted construct heals.

Applicants disagree. It is respectfully submitted that with submission of new claims, the double patenting is no longer an issue here as the claims are different from any and all the above cited references.

Double Patenting

Claims 2-5, 7-9 and 21-30 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 4-9, 12-17, 19 and 21-28 of copending Application No. 10/626,459. Although the conflicting claims are not identical, they are not patentably distinct from each other because the presently claimed method for repair and regeneration of articulator cartilage using a top sealant, or top and bottom sealants, would have been obvious from the claimed method of the copending application for repairing articular cartilage using top and bottom sealants.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicants disagree, however, to advance the prosecution, Applicants herewith submit the fully executed Terminal Disclaimer.

Double Patenting

Claims 2, 7-9 and 21-23 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 21-42 of copending Application No. 10/625,245 or claims 1-29 of copending Application No. 11/413,419 in view of Wise et al and Rhee et al ('052), and if necessary in

further view of Rhee et al ('519).

For the type of reasons set forth in the 103 rejection, it would have been obvious to seal a defect after implanting the cartilage construct of the claims of the copending applications using a sealant as suggested by Wise et al and Rhee et al ('052), and if needed Rhee et al ('519). Formation of a superficial cartilage layer will be inherent when the defect containing the sealed implanted construct heals.

This is a provisional obviousness-type double patenting rejection.

Applicants disagree, however, in the interest of advancing the prosecution, Applicants herewith submit the fully executed Terminal Disclaimers.

Finding of Claims Free of Prior Art

Applicants appreciate Examiner finding claims 3-5 and 24-30 free of the prior art. These claims are now redrafted as claims 32-42.

SUMMARY

In summary, applicants canceled claims 1-30 and submit herewith the new claims 31-42. These claims take in consideration Examiner's rejections under 35 USC 112, first and second paragraph as well as rejection under 35 USC 103 and Double Patenting. Applicants submit herewith arguments overcoming the rejection under 35 USC 102 and 103 Terminal Disclaimers are also submitted. With these amendments and arguments, it is believed that the claims are in conditions for allowance. Notice of Allowance is respectfully requested.

Respectfully submitted,

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